

REMARKS

This is a response to the Office Communication dated December 3, 2008.

Claims 26-30 are currently pending. Claim 26 is amended in the instant response, claim 30 is added. Claim 30 is supported by the specification, for example see claim 26.

The pending claims stand rejected under 35 USC 112, first paragraph, for lack of written description.

The description in the application along with the knowledge in the art at the time of filing would have led one of ordinary skill to conclude that Applicants were in possession of the claimed invention at the time of filing. There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). The Office has failed to overcome this assumption, but in order to hasten prosecution the Applicant has further limited the scope of our claims. The claims currently all meet the written description requirements as the Office has described them in the Written Description Guidelines (<http://www.uspto.gov/web/offices/pac/writtendesc.pdf>) which are provided by the Office as guidance to Examiners and Applicants. Please see, for example, examples 13 and 14 therein.

Generally, as the Office teaches, there is an inverse correlation between the level of skill in the art and the specificity required to satisfy the written description requirement. MPEP 2163. In the instant case, an understanding of the correlation between DNA sequence and protein sequence is taught even in non-majors college classes across the country. Gonick and Wheelis, *The Cartoon Guide to Genetics* (page 129 and following) 1983, HaperCollins, New York, NY, for example. The high level of skill in the art is also discussed in the recent BPAI decision Ex Parte Kubin (discussed below). The Applicants have further described and enabled the expression of chimeric genes in a variety of organisms (as discussed by the Office in the instant rejection at page 3, lines 1-3). Finally the Applicants have described and enabled the assay for determining Brittle-1 activity as discussed by the Office at page 4, line 7 and following in the instant rejection. The Office further admits that the specification is enabling for the nucleic acids as set forth (see the instant rejection at page 2, line 7 and page 4 line 7). The Office

then goes on to argue that the specification does not enable “variants” when the creation of variants is within the skill of the art (Ex Parte Kubin (BPAI Appeal 2007-0819, Application 09/667,859), and the testing of the native protein fulfills both the written description and enablement requirements as admitted by the Office at page 2, line 7 of the instant rejection. Deductive logic would seem to argue that the Office is arguing that either creating the protein is not within the skill of the art or that the testing of variants is sufficiently different from the testing of the native protein that the testing of variants is not described. Applicant believes that neither of these arguments is persuasive. Further, Applicant believes there is no undue experimentation as one of skill in the art would not test all possible variants, but only the few that they had a particular interest in or hypothesis about (this is fully supported by the Written Description Guidelines above).

“The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.” MPEP 2163.04.

As the instant claims all fulfill all statutory requirements of 35 USC 112, and meet the Written Description Guidelines and recent BPAI and other guidance provided by the Office, Applicant asks that all claims be allowed.

The claims were further rejected under 35 USC 103 as being unpatentable over Sullivan in view of Li.

As noted by the Office on page 6, line 17 of the instant rejection, Sullivan does “not teach nucleic acids that encode brittle-1 proteins with 90% or 95% identity to SEQ ID NO: 18.” Applicant believes that the sequence of the wheat gene cannot be anticipated by a general statement that it would be obvious “to isolate homologues” based on a sequence from another plant (this conclusion is supported by Ex Parte Kubin, see below). The claims are specifically limited to

the sequence of the wheat gene, or those sequences 95% similar, and this specific sequence (the wheat gene) cannot be anticipated by a general statement. A prima facie case of obviousness can be found where a chemical compound has close structural similarity as would have been obvious to one skilled in the art (MPEP2144.09), but since the structural similarity between DNA and protein sequences is unpredictable in foresight, Applicant believes this art, or combination thereof, does not make this invention obvious.

Further, Sullivan provides no motivation to search for a monocot Brittle-1 different from the maize gene in Sullivan. Sullivan simply clones corn genes, and does not state or imply a need in the art to search for genes from other sources.

Applicant respectfully believes that overcoming the primary reference in a two reference combination must, by logical deduction, overcome the combination as, in this case, the primary reference is required for the obviousness finding (e.g. without Sullivan the wheat gene is not anticipated, only the transit peptide) – the Office has not argued that Li is anticipating on its own. This is supported by case law and the MPEP. A prima facie case of obviousness requires that each and every limitation of a claim be anticipated. In an obviousness determination these anticipations can come from more than one reference, and they can be implied and not explicit under certain circumstances (*KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007)), BUT the Applicant need only show the prior art does not contain one limitation from one reference to make the claim nonobviousness, just as the Applicant would in an anticipation rejection under 102. The MPEP clearly states and supports this position at 706.02(j):

"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

As a final note, Applicant believes the Li reference is not prior art to this application under 35 USC 102(b), and thus cannot be used as prior art under 103

as 102(b) art. Li was published 9-15-2002, the instant application was filed on 9-10-2003.

The recent BPAI case of Ex Parte Kubin (BPAI Appeal 2007-0819, Application 09/667,859) may have relevance for the instant claims. In the case of Kubin, the BPAI found that the skilled artisan would have been motivated (under the obviousness standard) to isolate the NAIL cDNA when the exact same protein was already known, as an antibody to it had been produced, and a closely related DNA sequence was prior art (*ibid*, page 4). In Kubin the prior art reference also contained a prophetic example of how to isolate the cDNA (motivation that is lacking in the instant case). In the instant case the Office is arguing that finding a different gene, in a different organism, with a different sequence is made obvious by the prior finding of a similar homologous gene in a different organism, without both the motivation shown in Kubin as well as the antibody to the gene. Applicant believes that Kubin does not support the Office's position. Further, Kubin supports the conclusion the invention described herein is enabled (*ibid*, page 14).

Applicant asks that all claims be allowed.

Please charge any fees or credit any overpayment of fees which are required in connection with the filing of this Response to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

Allowance of the above-referenced application is respectfully requested in view of the foregoing.

Examiner is encouraged to call the undersigned to discuss this case with any question which has arisen herein.

Respectfully submitted,

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Dated: 3-02-09